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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,462	06/03/2005	Kenji Matsuda	Q88123	4737

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EXAMINER	
SOROUSH, LAYLA	
ART UNIT	PAPER NUMBER
1617	
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04/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,462	MATSUDA ET AL.	
	Examiner	Art Unit	
	LAYLA SOROUSH	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-9,11-13,15-21,23-25,27-29 and 31-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-9, 11-13, 15-21, 23-25, 27-29, and 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed February 6, 2008 presents remarks and arguments submitted to the office action mailed September 7, 2007 is acknowledged.

Applicant's arguments over the 35 U.S.C. 102(a) rejection of claims 1-5, 9, 13, 15, 18-21, 29, and 31 over Yamada et al. (Publication Date June 26, 2002), as evidenced by M Schneider (Chapter Seven Fractionation and Purification of Lecithin. Lecithins:Sources, Manufacture & Uses. Edited by Szuhaj1988 is not persuasive. Therefore, the rejection is maintained for the reasons of record.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 7-8, 11,12, 16, 23-25, 27, 28, 32 and 33 over Yamada et al. (Publication Date June 26, 2002), as evidenced by M Schneider (Chapter Seven Fractionation and Purification of Lecithin. Lecithins:Sources, Manufacture & Uses. Edited by Szuhaj.1988 and further in view of Unger et al. (US Pat. No. 6,090,800) is not persuasive. Therefore, the rejection is maintained for the reasons of record.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claim 17 over Yamada et al. (Publication Date June 26, 2002), in view of M Schneider (Chapter Seven Fractionation and Purification of Lecithin. Lecithins:Sources, Manufacture & Uses. Edited by Szuhaj.1988 and further in view of in view of Yugari (US 20010047162 A1) is persuasive. Therefore, the rejection is herewith withdrawn.

Claims 1-5, 7-9, 11-13, 15-21, 23-25, 27-29, and 31-33 are pending.

The rejections are restated below for applicants convenience:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 9, 13, 15, 18-21, 29, and 31 are rejected under 35 U.S.C. 102(a) as being anticipated by Yamada et al. (Publication Date June 26, 2002—provided in previous action), as evidenced by M Schneider (Chapter Seven Fractionation and Purification of Lecithin. Lecithins:Sources, Manufacture & Uses. Edited by Szuhaj.1988).

The claimed invention is a fat emulsion with which a local anesthetic is mixed before use, and which comprises propofol, an oily component, and an emulsifier, the fat emulsion further comprising a specific stabilizer. The limitation "pain relieving," recited in claims 18-20, 29, 31, and 32 is a preamble and receives no patentable weight.

Yamada et al. discloses a fat emulsion preparation (page 7 [a technical field and background art]) in example 1, comprising lidocaine (local anesthetic), propofol, soybean oils (oily component), and egg yolk lecithin (stabilizers and emulsifier) (pages 16 and 17 [0017]).

Yamada et al.'s Example 1, relied upon for the rejection, meets every limitation of claims 1-4, 13, 15, 16, 18-20, 29, 31, and 32. More specifically, Example 1 teaches:

- Lidocaine (local anesthetic)
- Propofol

- Soy bean oil (oily component)
- Yolk lecithin (stabilizer and emulsifier)
- Polyoxyethylene (6) hydrogenated castor oil (emulsifier)

M Schneider teaches egg lecithin comprises phosphatidylcholine and saturated and unsaturated fatty acid compositions inclusive of palmitic, stearic, oleic, linoleic, linolenic, and arachidonic. Therefore, yolk lecithin, in Yamada et al. inherently comprise the phosphatidylinositol, phosphatidylethanolamine and the C10-22 linear or branched, saturated or unsaturated fatty acids.

The composition taught in the prior art has a final concentration of 0.1-0.5 w/v% lidocaine (local anesthetic), 0.5-2.0 w/v % propofol, about 5-20 w/v % of vegetable oil (oily component), 0.5-5 w/v% of phospholipids, and 0.05-0.5 w/v% stabilizer and emulsifier), (page 16, paragraph [0015]). The claimed ranges overlap with the ranges taught by the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-8, 11,12, 16, 23-25, 27, 28, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada et al. (Publication Date June 26, 2002) in

view of M Schneider (Chapter Seven Fractionation and Purification of Lecithin. Lecithins:Sources, Manufacture & Uses. Edited by Szuhaj), as applied to claims 1-5, 9, 13, 15, 18-21, 29, and 31 and further in view of Unger et al. (US Pat. No. 6,090,800).

Yamada et al and M Schneider are as discussed above.

The limitation "pain relieving," recited in claims 21, 23-25, 27, and 28 is a preamble and receives no patentable weight.

Yamada et al. teaches phospholipids as a component of the fat emulsion composition in 0.5-5 w/v%. Therefore, the claimed ranges overlap with the ranges taught by the prior art reference.

Yamada does not specifically teach the composition comprising at least one phospholipid selected from the group consisting of phosphatidylglycerol, phosphatidic acid, phosphatidylinositol, and phosphatidylserine wherein the fatty acid esterified to glycerol moiety is a C18-22 linear or branched, saturated or unsaturated fatty acid nor at least one phospholipid derivative selected from phosphatidylethanolamines modified with polyalkyleneglycol, wherein a fatty acid esterified to a glycerol moiety is a C10-22 linear or branched, saturated or unsaturated fatty acid.

Unger et al. teaches distearoylphosphatidylglycerol (column 18, line 57) (claim 7), palmitic acid, stearic acid, oleic acid (column 18, lines 57-58), dioleoylphosphatidylethanolamine (column 23, line 5) and distearoylphosphatidylethanol-amine-polyethylene glycol 5000 (column 30, line 50-51) as suitable stabilizers in a drug composition.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to incorporate any phospholipid suitable for a drug composition into the claimed fat emulsion composition. The incorporation would have been motivated by the teachings in Unger et al. that the "stabilizers provide improved stability involving, for example, the maintenance of a relatively balanced condition, and may be exemplified, for example, by increased resistance of the composition against destruction, decomposition, degradation, and the like (column 6 lines 59-67 and column 7 lines 1-3)." Therefore the skilled artisan would have had a reasonable expectation of producing a similar composition, which yields the same efficacy and properties as taught in the prior art references.

In reference to claim 33, the term "mixing" is within the purview of a skilled artisan. The composition as claimed is anticipated by the prior art reference and the method of mixing is obvious to one of ordinary skill in the art.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada et al. (Publication Date June 26, 2002) as applied to 1-5, 9, 13, 15, 18-21, 29, and 31 above, and further in view of Yugari (US 20010047162 A1).

Yamada et al is as discussed above.

Yamada et al. does not expressively teach the fat emulsion containing container having a multi-compartment that is divided with a partition in such a manner as to allow the compartments to communicate with one another, which container comprises one

compartment containing the fat emulsion and another compartment containing a local anaesthetic.

Yugari teaches an injection kit "made of multiple layered flexible plastic bag formed cylindrically (soft bag), and is separated into compartments by one or plural welded partition easy-to-peel seal." Further, the reference teaches different liquid medicine can be kept in each separated compartment and the pressure can break the partition seals, just prior to its use. An example of a liquid (solvent) contained in a compartment is a fat emulsions.

It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to incorporate the fat emulsion into the claimed container. The incorporation would have been motivated by the teaching in Yugari that the injection kit enables to inject to a patient directly upon the preparation of the solution with the kit. Therefore the skilled artisan would have had a reasonable expectation of producing a similar effect as taught in the prior art reference.

Response to Arguments

Applicant's arguments filed February 6, 2008 have been fully considered.

Applicant argues that the teaching of Yamada et al. is different from the claimed invention because the stabilizers utilized in the examples are different from the claimed limitations of (a) to (d). Further Applicant argues that M. Schnider states "unsaturated fatty acids are predominantly bound to the two-position of the glycerol backbone of both triglycerides and phospholipids." Hence the fatty acids are bound to the main chain of phoshpatidylcholine.

In response, the prior art in fact teaches "unsaturated fatty acids are predominantly bound to the two-position of the glycerol backbone of both triglycerides and phospholipids." Hence the prior art teaches not all unsatruated fatty are bound, therefore, reading on free unsaturated fatty acids.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, applicant argues that Unger et al. teaches " a wide range of lipids as stabilizers are used for pharmaceutical compositions." Examiner states that Unger is solely used to show that the claimed lipids as stabilizers are well known in the prior art to be used in pharmaceutical compositions. Also, Examiners position is that it would have been obvious to combine the teachings of the prior art reference because Yamada teaches the injectable anesthetic, while Yugari teaches an injectable container for fat emulsions to be kept in a departmentalized unit. Further, Yugari teaches one compartment may contain a fat emulsion (paragraph [0109]). The motivation to incorporate the injection kit of Yugari is because it enables one to prepare an injection solution speedily, easily, safely and aseptically, by dissolving a solid medicine for intravenous, intra-muscular, hypodermic and intra-dermal injections (page 1, paragraph [0009]).

The arguments are not persuasive and the rejection is made **FINAL**.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617